

REMARKS:

Applicant thanks Examiner Krishnan for his time and consideration of the present application during the telephonic interview of August 23, 2011 with the undersigned.

During the interview, the undersigned explained that the further preliminary amendment filed July 3, 2007 was necessary to correct the formula for Trehalose and its corresponding derivatives application, as evidenced by the document provided in the appendix of said amendment. Examiner Krishnan agreed that said amendment did not introduce new matter.

This application has been further amended to place it in condition for allowance at the time of the next Official Action.

Status of the Claims

Claims 24, 26, 29-35, 38-43, 46 and 47 have been amended formally to clarify the claimed features.

Substantive amendments to the claims include the following:

Claim 24 has been amended to include R_1 and R_2 in formula I, i.e., consistent with the preliminary amendment to the specification (filed July 3, 2007) at the paragraph beginning at page 2, line 24. Additionally, three particular values for R_1 and R_2 are recited: palmitic acyl, stearic acyl and hydroxyphthioceranoic acyl (i.e., as previously recited in claim 25).

Claims 32-43 are amended to clarify the meaning of mixture in view of the discussion on page 9, beginning at line 6.

Claims 38 and 39 are amended to clarify the "other products" in a manner consistent with page 10, lines 23-17.

Claims 25, 44 and 45 have been cancelled without prejudice.

Claims 24, 26-43, 46 and 47 remain in this application.

Claim 46 is indicated as being withdrawn, but rejoinder of this claim is requested for the reasons discussed below.

Election/Restriction

The rejoinder of claims 41-43 and claims 24, 26-40 and 47 is acknowledged with appreciation.

Claims 44 and 45 have been cancelled, and their subject matter has been incorporated into claim 46. Claim 46 is further amended to depend from claim 24, i.e., the process is directed the extraction of a compound according to claim 24.

Therefore, claim 46 shares the same technical feature as claim 24, and rejoinder of claim 46 with claims 24, 26-43 and 47 is respectfully requested.

Claim Objections

Claim 38 was objected to because the notation BCG should be expanded.

Claim 38 has been amended to recite Bacillus of Calmette and Guerin, and, thus, withdrawal of the objection should be respectfully requested.

Specification

The amendment filed July 3, 2007 was objected to under 35 U.S.C. 132(a) because it allegedly introduced new matter into the disclosure.

However, as discussed during the telephonic interview of August 23, 2011, the amendment did not introduce new matter. Instead, the amendment was necessary to correct the formula for Trehalose and its corresponding derivatives application, as evidenced by the document provided in the appendix of the amendment of July 3, 2007.

Therefore, withdrawal of this objection is respectfully requested.

Claim Rejections-35 USC §112

Claims 24-43 and 47 were rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. This rejection is respectfully traversed for the reasons below.

The position was based on two issues:

(1) The compounds of formulae (I)-(III) allegedly do not correspond to the compounds disclosed in the specification as filed.

However, as the above mentioned correction to the specification and claims did not introduce new matter.

(2) The scope of the claimed formulae compared to the scope of the disclosure.

Claim 24 is now directed to three particular values for R_1 and R_2 : palmitic acyl, stearic acyl and hydroxyphthioceranoic acyl. This claimed invention is believed to be within the scope of the disclosure.

Therefore, claim 24 and, thus, the dependent claims comply with the written description requirement, and withdrawal of the rejection is respectfully requested.

Claims 38-40 were rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement. This rejection is respectfully traversed for the reasons below.

The position was that while being enabling for the treatment of tuberculosis, the specification does not reasonably provide enablement for the prophylaxis of tuberculosis as recited in the instant claims.

With respect to this position, the Examiner's attention is respectfully directed to the Declaration under 37 CFR 1.132 by Germain PUZO, one of the named inventors of the present

application, included in the Appendix. The declaration discusses example 3 of the present specification as support of the enablement requirement.

Example 3 discloses *ex vivo* assays which illustrate the immunogenicity of the sulfoglycolipids (compounds of claim 24). This example thus constitutes a sufficient basis and reasonable scientific rationale for supporting the use of the claimed compounds in a vaccine and, as such, the prevention of tuberculosis.

Therefore, the claims do comply with the enablement requirement, and withdrawal of the rejection is respectfully requested.

Claims 24-43 and 47 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite. This rejection is respectfully traversed for the reasons below.

Claim 24 was rejected for reciting substituents R_1 and R_2 being fatty acyl groups, but formula I did not include these substituents. The present amendment corrects this error, and includes R_1 and R_2 in formula I consistent with the preliminary amendment to the specification (filed July 3, 2007) at the paragraph beginning at page 2, line 24.

Claims 25-35 were rejected because claim 24 recites "a compound". The dependent claims refer to the compound of claim 24.

Claims 32 and 38 were rejected for reciting "such as", which has now been removed from these claims.

Claim 32 was also rejected for reciting two different compounds of formula I, whereas a single compound of formula I is recited in parent claim 24. This also applied to claims 33-43 and 47. The claimed "composition" may comprise a number of compounds that fall within the broad definition of formula I of claim 24, but these compounds may differ by the R_1 and R_2 , e.g., as exemplified in claims 26-31. That is, for the compound of formula I, either of the R groups could be hydroxyphthioceranoic acyl, which may further vary by the m and n subscripts, or either of these R groups could be palmitic acyl (i.e., $p=14$) or stearic acyl ($p=16$). The claims have been further amended to clarify that the different compounds fall within the broader definition of formula I.

Claims 38 and 39 were rejected for reciting "other products" the definite examples stated on page 10, lines 23-27 are now recited in these claims.

Therefore, in view of the above, withdrawal of the rejection is respectfully requested.

Claim Rejections-35 USC §102

Claims 24, 36-39 were rejected under 35 U.S.C. 102(b) as being anticipated by DESMARAIS et al. (J. Bacteriology, 1997, 3146-53 (DESMARAIS)). This rejection is respectfully traversed for the reasons below.

DESMARAIS does not disclose compounds according to formula I of claim 24, wherein OR_1 and OR_2 are different from OH.

Thus, DESMARAIS fails to anticipate any compound according to claim 24, or at least one compound according to claim 24 as recited in claims 36-39.

Therefore, withdrawal of the rejection is respectfully requested.

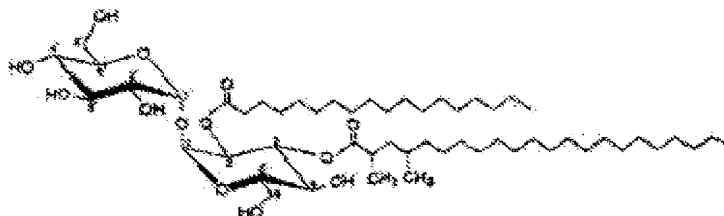
Claim Rejections-35 USC §103

Claims 24-37 and 40-43 were rejected under 35 U.S.C. 103(a) as being unpatentable over VERGNE et al. Frontiers in Bioscience (VERGNE) in view of BESRA et al. Biochemistry (BESRA).

Claims 38 and 39 were rejected under 35 U.S.C. 103(a) as being unpatentable over VERGNE in view of BESRA, further in view of the Merck Manual.

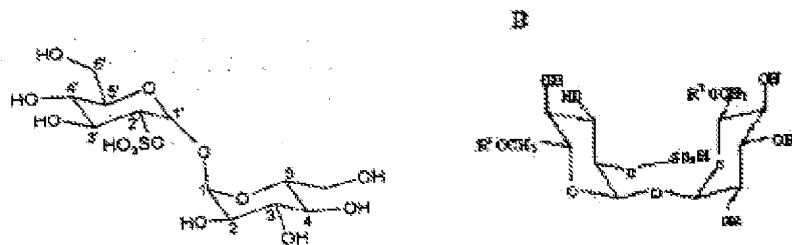
These rejections are respectfully traversed for the reasons below.

VERGNE discloses the following diacyltrehalose (figure 8, page 9836):



The compounds of the claimed invention differ from those of VERGNE by the presence of the group $-OSO_3H$ in the 2' position of the trehalose.

BESRA discloses the following compounds (figure 1, page 866):



The compounds of BESRA differ from those of the present claims by the fatty acyl groups substituted for wherein R₁ and R₂.

The position of the Official Action was that claim 24 would have been obvious in view of BESRA combined with VERGNE. In particular, the Action alleges that it would have been obvious in view of BESRA which concerns compounds with a sulfate group in the 2' position and fatty acyl groups, combined with VERGNE which discloses compounds with a fatty acyl group in positions 2 and 3 to achieve the compounds of the invention.

According to the claimed invention, the sulfoglycolipid comprises in the 2' position a sulfate group and in positions 2 and 3 specific fatty acyl groups.

None of the cited documents neither discloses nor suggest compounds which combine:

- in position 2': a sulphate group, and
- in positions 2 and 3: specific fatty acyl groups
such as R₁ and R₂.

Further, even if the skilled person would have considered compounds comprising, simultaneously, both sulfate groups and fatty acyl groups, there was no suggestion at all

that these compounds would have an improved activity against tuberculosis, as apparent from the results given in the specification.

Regardless of its ability to teach that for which it was offered, Merck Manual is not able to remedy the shortcomings of VERGNE and BESRA for reference purposes.

Therefore, withdrawal of the rejection of claims 24-37 and 40-43 is respectfully requested.

Claim 47 was rejected under 35 U.S.C. 103(a) as being unpatentable over BESRA alone. This rejection is respectfully traversed for the reasons that follow.

The process of extracting compounds according to claim 24 should be non-obvious, as the compounds of claim 24 are neither anticipated by DESMARAIS nor render obvious over the combination of VERGNE and BESRA with or without the Merck Manual.

Therefore, withdrawal of the rejection is respectfully requested.

Double Patenting

Claims 24-43 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30-31, 37-38, 40, 42-46 and 48 of copending Application No. 12/524,091 ('091).

This rejection is respectfully traversed on the basis that the compounds of the present claims are structurally

different in view of the corrected structure from the preliminary amendment of July 3, 2007 and in view of the specific definitions of R_1 and R_2 .

Therefore, withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claims, the Declaration included in the Appendix and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item:

- a 37 CFR 1.132 Declaration